

<b>LIST OF PRIOR ART CITED BY APPLICANT</b> (PTO-1449)	ATTY. DOCKET NO. <b>CI-0008</b>	APPLN. SERIAL NO. <b>09/960,701</b>
	<b>APPLICANT(S)</b> David M. MANN, William N. DROHAN, Martin J. MORHEE and Wilson BURGESS	
	FILING DATE <b>September 24, 2001</b>	GROUP <b>1744 JAN 24 8 2002</b>



**RECEIVED**

### U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILED DATE
LM	RE. 23,195	02/1950	Arno Brasch			
	2,832,689	04/1958	Bernard E. Proctor et al.			
	2,920,969	01/1960	E.S. Stoddard			
	2,962,380	11/1960	J.H. Wertheim			
	3,620,944	11/1971	Keiko Tanito			
	3,743,480	07/1973	John D. Falk			
	3,779,706	12/1973	Nablo			
	4,136,094	01/1979	Condie			
	4,251,437	02/1981	Rasmussen et al.			
	4,282,863	08/1981	Beigler et al.			
LM	4,330,626	05/1982	Blair et al.			

### U.S. PATENT APPLICATION PUBLICATIONS

	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS	

### U.S. PATENT APPLICATIONS

	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	

### FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
LM	2,056,619	10/1991	Canada				
	0 310 316	04/1989	Europe				
	0 334 679	09/1989	Europe				
	WO 90/00907	02/1990	PCT Int'l.				
	WO 91/16060	10/1991	PCT Int'l.				
LM	WO 95/03071	02/1995	PCT Int'l.				

### OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)

LM	AABB FDA Liaison Meeting, ABC Newsletter, December 12, 1997, pps. 14
LM	Tikvah Alper et al., The Exceptionally Small Size of the Scrapie Agent, 1966, pps. 278-284, Biochemical and Biophysical Research Communications, Vol. 22, No. 3

EXAMINER	DATE CONSIDERED
KmcLane	9/22/03

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

				ATTY. DOCKET NO. CI-0008		APPLN. SERIAL NO. 09/960,701	
				APPLICANT(S) David M. MANN, William N. DROHAN, Martin J. MCPHEE and Wilson BURGESS		FILING DATE September 24, 2001	
						GROUP 1741	
<b>U.S. PATENT DOCUMENTS</b>							
EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE	
LM	4,370,264	01/1983	Kotitschke et al.			TC 1700	
	4,409,105	10/1983	Hayashi et al.				
	4,472,840	09/1984	Jefferies				
	4,620,908	11/1986	Van Duzer				
	4,933,145	06/1990	Uchida et al.				
	4,946,648	08/1990	Dichtelmüller et al.				
	4,963,356	10/1990	Calenoff et al.				
	5,000,951	03/1991	Bass et al.				
	5,106,619	04/1992	Wiesehahn et al.				
	5,134,295	07/1992	Wälichschmiller				
LM	5,185,371	02/1993	Rubinstein				
<b>U.S. PATENT APPLICATION PUBLICATIONS</b>							
	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS		
<b>U.S. PATENT APPLICATIONS</b>							
	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS		
<b>FOREIGN PATENT DOCUMENTS</b>							
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>							
LM	Tikvah Alper et al., Protection by Anoxia of the Scrapie Agent and Some DNA and RNA Viruses Irradiated as Dry Preparations, 1968, pps. 157-166, J. gen. Virol., Vol. 3						
LM	Tikvah Alper et al., Does the Agent of Scrapie Replicate Without Nucleic Acid? May 20, 1967, pps. 764-766, Nature, Vol. 214						
LM	Tikvah Alper et al., The Scrapie Agent: Evidence Against its Dependence For Replication on Intrinsic Nucleic Acid, 1978, pps. 503-516, J. gen. Virol., Vol. 41						
EXAMINER	DATE CONSIDERED			9/25/03			

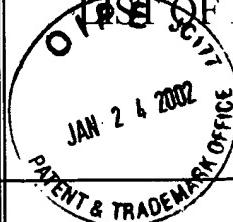
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

 <b>LIST OF PRIOR ART CITED BY APPLICANT</b> (PTO-1449)			ATTY. DOCKET NO. <b>CI-0008</b>	APPLN. SERIAL NO. <b>09/960,701</b>		
			APPLICANT(S) David M. MANN, William N. DROHAN, Martin J. MACPHEE and Wilson BURGESS			
			FILING DATE <b>September 24, 2001</b>	GROUP <b>1741</b>		
<b>RECEIVED</b> JAN 28 2002 <b>TC 1700</b>						
<b>U.S. PATENT DOCUMENTS</b>						
EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
LM	5,226,065	07/1993	Held et al.			
	5,362,442	11/1994	Kent			
	5,418,130	05/1995	Platz et al.			
	5,460,962	10/1995	Kemp			
	5,510,122	04/1996	Sreebny et al.			
	5,603,894	02/1997	Aikus et al.			
	5,609,864	03/1997	Shanbrom			
	5,637,451	06/1997	Ben-Hur et al.			
	5,712,086	01/1998	Horowitz et al.			
	5,730,933	03/1998	Peterson			
LM	5,817,528	10/1998	Böhm et al.			
<b>U.S. PATENT APPLICATION PUBLICATIONS</b>						
	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS	
<b>U.S. PATENT APPLICATIONS</b>						
	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	
<b>FOREIGN PATENT DOCUMENTS</b>						
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation Yes No
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>						
LM	Michael L. Baldwin et al., Irradiation of Blood Components, 1992, pps. 1-78, American Association of Blood Banks					
LM	R.H. Bassin et al., Abrogation of Fv-1 <sup>b</sup> Restriction With Murine Leukemia Viruses Inactivated by heat or by Gamma Irradiation, May 1978, pps. 306-315, Journal of Virology, Vol. 26, No. 2					
LM	Guy Beauregard et al., Temperature Dependence of the Radiation Inactivation of Proteins, 1985, pps. 117-120, Analytical Biochemistry, Vol. 150					
EXAMINER	<i>R. McCabe</i>		DATE CONSIDERED <i>9/25/03</i>			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

 <b>PRIOR ART CITED BY APPLICANT</b> (PTO-1449)				ATTY. DOCKET NO. <b>CI-0008</b>	APPLN. SERIAL NO. <b>09/960,701</b>	
				APPLICANT(S) <b>David M. MANN, William N. DROHAN, Martin J. MACPHERSON and Wilson BURGESS</b>		
				FILING DATE <b>September 24, 2001</b>	GROUP <b>1741</b>	
<b>U.S. PATENT DOCUMENTS</b>						
EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
LM	5,837,313	11/1998	Ding et al.			
	5,881,534	03/1999	Ahlqvist et al.			
	5,981,163	11/1999	Horowitz et al.			
	5,986,168	11/1999	Noishiki			
	6,046,024	04/2000	Burton et al.			
	6,049,025	04/2000	Stone et al.			
	6,066,626	05/2000	Yew et al.			
	6,087,141	07/2000	Margolis-Nunno et al.			
	6,120,592	09/2000	Brault et al.			
	6,159,490	12/2000	Deghenghi			
LM	6,171,549	01/2001	Kent			
<b>U.S. PATENT APPLICATION PUBLICATIONS</b>						
	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS	
<b>U.S. PATENT APPLICATIONS</b>						
	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	
<b>FOREIGN PATENT DOCUMENTS</b>						
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation Yes No
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>						
LM	David R. Brown et al., Antioxidant Activity Related to Copper Binding of Native Prion Protein, 2001, pps. 69-76, Journal of Neurochemistry, Vol. 76					
LM	P. Brown, The Risk of Blood-Borne Creutzfeldt-Jakob Disease, 1999, pps. 53-59, Advances in Transfusion Safety Dev. Biol. Vol. 102					
LM	P. Brown et al., Further Studies of Blood Infectivity in an Experimental Model of Transmissible Spongiform Encephalopathy, With an Explanation of Why Blood Components Do Not Transmit Creutzfeldt-Jakob Disease in Humans, November/December 1999, pps. 1169-1178, Transfusion, Vol. 39					
EXAMINER <i>L. MacCabe</i>	DATE CONSIDERED <b>9/25/03</b>					

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

 <b>LIST OF PRIOR ART CITED BY APPLICANT</b> (PTO-1449)			ATTY. DOCKET NO. <b>CI-0008</b>		APPLN. SERIAL NO. <b>09/960,701</b>	
			APPLICANT(S) David M. MANN, William N. DROHAN, Michael J. MACPHEE and William BURGESS			
			FILING DATE <b>September 24, 2001</b>	GROUP <b>1741</b>		RECEIVED <b>JAN 28 2002</b>
<b>U.S. PATENT DOCUMENTS</b>						
EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	*FILING DATE
LM	6,187,572	02/2001	Platz et al.			
	6,190,855	02/2001	Herman et al.			
	6,197,207	03/2001	Chapman et al.			
	6,214,534	04/2001	Horowitz et al.			
LM	6,235,508	05/2001	Sowemimo-Coker et al.			
<b>U.S. PATENT APPLICATION PUBLICATIONS</b>						
	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS	
<b>U.S. PATENT APPLICATIONS</b>						
	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	
<b>FOREIGN PATENT DOCUMENTS</b>						
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation Yes      No
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>						
LM	Paul Brown et al., Effect of Chemicals, Heat, and Histopathologic Processing on High-Infectivity Hamster-Adapted Scrapie Virus, May 1982, pps. 683-687, The Journal of Infectious Diseases, Vol. 145, No. 5					
LM	P. Brown et al., The Distribution of Infectivity in Blood Components and Plasma Derivatives in Experimental Models of Transmissible Spongiform Encephalopathy, September 1998, pps. 810-816, Transfusion, Vol. 38					
LM	Derwent Publication AN - 111469, prior art.					
EXAMINER <i>L. McCabe</i>	DATE CONSIDERED <i>9/25/03</i>					

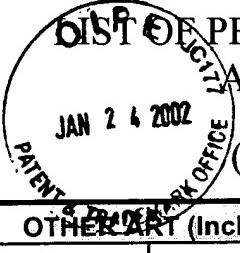
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

<b>LIST OF PRIOR ART CITED BY APPLICANT</b> (PTO-1449) <p style="text-align: right;"><i>O P E R A T I O N S C E N T E R</i> <i>JAN 24 2002</i> <i>PATENT &amp; TRADEMARK OFFICE</i></p>				ATTY. DOCKET NO. CI-0008		APPLN. SERIAL NO. 09/960,701
				APPLICANT(S) David M. MANN, William N. DROHAN, Martin J. MCKEE and William BURGESS		
				FILING DATE September 24, 2001		GROUP 1741
<b>U.S. PATENT DOCUMENTS</b>						
EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
<b>U.S. PATENT APPLICATION PUBLICATIONS</b>						
	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS	
<b>U.S. PATENT APPLICATIONS</b>						
	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	
<b>FOREIGN PATENT DOCUMENTS</b>						
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation <input type="checkbox"/> Yes <input type="checkbox"/> No
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>						
LM	Derwent Publication - AN 2159557, prior art.					
	Derwent Publication - AN 2526936, prior art.					
	P. Di Simplicio et al., The Reactivity of the SH Group of Bovine Serum Albumin With Free Radicals, 1991, pps. 253-262, Free Rad. Res. Comms., Vol. 14, No. 4					
	Duane C. Eichler et al., Radiation Inactivation Analysis of Enzymes, July 15, 1987, pps. 9433-9436, The Journal of Biological Chemistry, Vol. 262, No. 20					
	Luanne H. Elliott et al., Inactivation of Lassa, Marburg, and Ebola Viruses by Gamma Irradiation, Oct. 1982, pps 704-708, Journal of Clinical Microbiology, Vol. 16, No. 4					
	Fields et al., Susceptibility of Scrapie Agent to Ionizing Radiation, April 5, 1969, pps. 90-91, Nature, Vol. 222					
	D.A. Haig, Further Studies on the Inactivation of the Scrapie Agent by Ultraviolet Light, 1969, pps. 455-457, J. gen. Virol., Vol. 5					
LM	H. Hiemstra et al., Inactivation of Human Immunodeficiency Virus by Gamma Radiation and its Effect on Plasma and Coagulation Factors, 1991, pps. 32-39, Transfusion, Vol. 31, No. 1					
EXAMINER <i>L. McKee</i>			DATE CONSIDERED 9/25/03			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

<b>LIST OF PRIOR ART CITED BY APPLICANT</b> <small>JAN 24 2002</small> <small>PTO-1449</small>		ATTY. DOCKET NO. <b>CI0008</b>	APPLN. SERIAL NO. <b>09/960,701</b>
		APPLICANT(S) David M. MANN, William N. DROHAN, Martin J. MAGUIRE and Winsn BURGESS	
		FILING DATE <b>September 24, 2001</b>	GROUP <b>1741</b>
<b>RECEIVED</b> <small>JAN 28 2002</small> <small>TC 1700</small>			
<b>OTHER ART</b> (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)			
LM	B. Horowitz et al., Inactivation of Viruses in Labile Blood Derivatives, II. Physical Methods, 1985, pps. 523-527, Transfusion, Vol. 25, No. 6		
	Carol House et al., Inactivation of Viral Agents in Bovine Serum by Gamma Irradiation, 1990, pps. 737-740, Can. J. Microbiol., Vol. 36		
	E.S. Kempner et al., Size Determination of Enzymes by Radiation Inactivation, 1979, pps. 2-10, Analytical Biochemistry, Vol. 92		
	J.D. Keathley et al., Is There Life After Irradiation? Part 2: Gamma-Irradiated FBS in Cell Culture, July/August 1993, pps. 46-52, BioPharm		
	A.D. Kitchen, Effect of Gamma Irradiation on the Human Immunodeficiency Virus and Human Coagulation Proteins, 1989, pps. 223-229, Vox Sang, Vol. 56		
	Raymond Latarjet, Inactivation of the Agents of Scrapie, Creutzfeldt-Jakob Disease, and Kuru by Radiations, 1979, pps. 387-407, Slow Transmissible Diseases of the Nervous System, Vol. 2		
	R. Latarjet et al., Inactivation of the Scrapie Agent by Near Monochromatic Ultraviolet Light, September 26, 1970, pps. 1341-1343, Nature, Vol. 227		
	Douglas C. Lee et al., A Direct Relationship Between the Partitioning of the Pathogenic Prion Protein and Transmissible Spongiform Encephalopathy Infectivity During the Purification of Plasma Proteins, April 2001, pps. 449-455, Transfusion, Vol. 41		
	Susan F. Leitman, Use of Blood Cell Irradiation in the Prevention of Posttransfusion Graft-vs-Host Disease, 1989, pps. 219-232, Transfus. Sci., Vol. 10		
	Linda Marton et al., Disinfection and Inactivation of the Human T. Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus, August 1985, pps. 400-403, The Journal of Infectious Diseases, Vol. 151, No. 2		
	S.I. Miekka et al., New Methods for Inactivation of Lipid-enveloped and Non-enveloped Viruses, 1998, pps. 402-408, Haemophilia, Vol. 4		
	Z. Mark Plavsic et al., Resistance of Porcine Circovirus to Gamma Irradiation, April 2001, pps. 32-36, BioPharm		
LM	Pollard, The Effect of Ionizing Radiation on Viruses, pps. 65-71, prior art.		
EXAMINER <i>L. McCane</i>	DATE CONSIDERED <i>9/25/03</i>		

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

 <b>LIST OF PRIOR ART CITED BY APPLICANT</b> (PTO-1449)		ATTY. DOCKET NO. <b>CI0008</b>	APPLN. SERIAL NO. <b>09/960,701</b>
		<b>APPLICANT(S)</b> David M. MANN, William N. DROHAN, Martin J. MACPHEE and Wilson BURGESS	
		FILING DATE <b>September 24, 2001</b>	GROUP <b>1741</b>
<b>RECEIVED</b> <b>JAN 28 2002</b> <b>TG 700</b>			
<b>OTHER CITE (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>			
LM	Elena Quaglio et al., Copper Converts the Cellular Prion Protein Into a Protease-resistant Species That Is Distinct From the Scrapie Isoform, April 6, 2001, pps. 11432-11438, The Journal of Biological Chemistry, Vol. 276, No. 14		
	Brian D. Reid, The Sterways Process: a New Approach to Inactivating Viruses Using Gamma Radiation, 1998, pps. 125-130, Biologicals, Vol. 26		
	Robert G. Rohwer, Estimation of Scrapie Nucleic Acid MW From Standard Curves for Virus Sensitivity to Ionizing Radiation, March 27, 1986, pp. 381, Nature, Vol. 320, No. 6060		
	Robert G. Rohwer, Scrapie Infectious Agent is Virus-like in Size and Susceptibility to Inactivation, April 12, 1984, pps. 658-662, Nature, Vol. 308		
	R.G. Rohwer, The Scrapie Agent: "A Virus by Any Other Name", pps. 195-232, Current Topics In Microbiology and Immunology, Vol 172, <u>prion art</u> .		
	Robert G. Rohwer et al., Scrapie - Virus or Viroid, The Case For A Virus, pps. 333-355, Laboratory of Central Nervous System Studies, National Institutes of Neurological and Communicative Disorders and Stroke, National Institutes of Health, <u>prion art</u> .		
	Robert G. Rohwer, Virus-Like Sensitivity of the Scrapie Agent to heat Inactivation, February 10, 1984, pps. 600-602, Science, Vol. 223		
	Robert Sullivan et al. Inactivation of Thirty Viruses by Gamma Radiation, July 1971, pps. 61-65, Applied Microbiology, Vol. 22, No. 1		
	Boon-Seng Wong et al., Copper Refolding of Prion Protein, 2000, pps. 1217-124, Biochemical and Biophysical Research Communications, Vol. 276		
	Boon-Seng Wong et al., Differential Contribution of Superoxide Dismutase Activity by Prion Protein in Vivo, 2000, pps. 136-139, Biochemical and Biophysical Research Communications, Vol 273		
	Boon-Seng Wong et al., Prion Disease: A Loss of Antioxidant Function? 2000, pps. 249-252, Biochemical and Biophysical Research Communications, Vol. 275		
	D.E. Wyatt et al., Is There Life After Irradiation? Part I: Inactivation of Biological Contaminants, June 1993, pps 34-39, BioPharm		
LM	License Amendment and Procedures for Gamma Irradiation of blood Products, June 22, 1993, pps. 1-18, Dept. of Health & Human Services, Food and Drug Administration		
EXAMINER <i>L. McKane</i>	DATE CONSIDERED <i>9/25/03</i>		

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

LIST OF PRIOR ART CITED BY APPLICANT (PTO-1449)		ATTY. DOCKET NO. CI-0008	APPLN. SERIAL NO. 09/960,701
		APPLICANT(S) David M. MANN, William N. DROHAN, Martin J. MACPHERSON and William BURGESS	
		FILING DATE September 24, 2001	GROUP 1741
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>			
<i>W.M.</i> <i>PTO-1449</i> <i>JAN 24 2002</i> <i>PATENT &amp; TRADEMARK OFFICE</i>	M.F. Alladine et al., $\gamma$ -Radiation Damage to Starr-Edwards Valves, March 16, 1968, pp. 68, The Lancet Letters to the Editor		
	Ch. Baquey et al., Radiosterilization of Albuminized Polyester Prostheses, May 1987, pps. 185-189, Biomaterials, Vol. 8		
	Edward H. Bedrossian, Jr., HIV and Banked Fascia Lata, 1991, pps. 284-288, Ophthalmic Plastic and Reconstructive Surgery, Vol. 7, No. 4		
	Liu Bingci, Mouse Antibody Response Following Repetitive Injections of Gamma-Irradiated human Placenta Collagen, June 1994, pps. 100-103, Chinese Medical Sciences Journal, Vol. 9, No. 2		
	E.A. Borisov et al., Protein Degradation During Interphase Death of Thymocytes Induced by Radiation and Dexamethasone, 1990, pps. 519-521		
	R.G. Burwell, The Fate of Freeze-Dried Bone Allografts, June 1976, pps. 95-111, Transplantation Proceedings, Vol. VII, No. 2, Supplement 1		
	L. Callegaro et al., Hollow Fiber Immobilized L-Asparaginase: In Vivo and In Vitro Immunological Studies, 1983, pps. 91-96, The International Journal of Artificial Organs, Vol. 6, No. 2		
	G. Campalani et al., Aortic Valve Replacement With Frozen Irradiated Homografts, 1989, pps. 558-561, Eur. J. Cardio-thoracic Surgery, Vol. 3		
	David T. Cheung et al., The Effect of $\gamma$ -Irradiation on Collagen Molecules, Isolated $\alpha$ -chains, and Crosslinked Native Fibers, 1990, pps. 581-589, Journal of Biomedical Materials Research, Vol. 24		
	David J. Cohen et al., The Fate of Aortic Valve Homografts 12 to 17 Years After Implantation, March 1988, pps 482-484, Chest, Vol. 93, No. 3		
	A.G. Chuchalin et al., Clinical Immunosorbents Basing On Space-Network Polymers, 1998, pps. 1524-1529, All Union Research Institute of Chemical Reagents and Chemicals of Special Purity, Moscow		
	P. De Deyne et al., Some Effects of Gamma Irradiation on Patellar Tendon Allografts, 1991, pps. 51-62, Connective Tissue Research, Vol. 27		
	E.A. Dyskin et al., Hemomicrocirculatory Bed in the Wall of Hollow Organs of the Dog Gastrointestinal Tract at Portal Hypertension, pps. 68-73, <i>prior art</i> .		
	R. Guidoin et al., A Compound Arterial Prosthesis: The Importance of the Sterilization Procedure on the Healing and Stability of Albuminized Polyester Grafts, March 1985, pps. 122-128, Biomaterials, Vol. 6		
	Ph. Hernigou et al., Radiation Sterilization of Bone and the HIV Virus, 1993, pps. 445-451, Revue de Chirurgie Orthopedique, Vol. 79		
	Hsing-Wen Sung et al. Effects of Various Chemical Sterilization Methods on the Crosslinking and Enzymatic Degradation Characteristics of an Epoxy-Fixed Biological Tissue, December 1996, pps. 376-383, Sterilization of Biological Tissues		
	James R. Malm et al., An Evaluation of Aortic Valve Homografts Sterilized by Electron Beam Energy, October 1967, pps. 471-477, Journal of Thoracic and Cardiovascular Surgery, Vol. 54, No. 4		
<i>W.M.</i>	James R. Malm et al., Results of Aortic Valve Replacement Utilizing Irradiated Valve Homografts, pps 740-747, Annals New York Academy of Sciences, <i>prior art</i> .		
EXAMINER <i>L. McCane</i>	DATE CONSIDERED <i>9/25/03</i>		

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

LIST OF PRIOR ART CITED BY APPLICANT (PTO-1449)		ATTY. DOCKET NO. <b>CI-0008</b>	APPLN. SERIAL NO. <b>09/960,701</b>
		APPLICANT(S) <b>David M. MANN, William N. DROHAN, Martin J. MACPHEE and Wilson BURGESS</b>	<i>RECEIVED JAN 28 2002</i>
		FILING DATE <b>September 24, 2001</b>	GROUP <b>1741</b>
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>			
<i>IP RESEARCH &amp; TRADE MARK OFFICE</i> <i>JAN 26 2002</i>	W. Oh et al., Mitral Valve Replacement With Preserved Cadaveric Aortic Homografts, May 1970, pps. 712-721, The Journal of Thoracic and Cardiovascular Surgery, Vol. 65, No. 5		
	K. Pietrucha, New Collagen Implant As Dural Substitute, April 1991, pps. 320-323, Biomaterials, Vol. 12		
	Maria Raptopoulou-Gigi et al., Antimicrobial Proteins in Sterilised Human Milk, January 1, 1977, pps. 12-14, British Medical Journal, Vol. 1		
	Edward A. Rittenhouuse et al., Sterilization of Aortic Valve Grafts for Transplantation, July 1970, pps. 1-5, Aortic Valve Grafts for Transplantation, Archives of Surgery, Vol. 101, No. 1		
	H. Sato et al., Sterilization of Therapeutic Immunoabsorbents by Ionizing Radiation, 1986, pps. 131-136, The International Journal of Artificial Organs, Vol. 9, No. 2		
	Richard A. Smith et al., Gamma Irradiation of HIV-1, 2001, pps. 815-819, Journal of Orthopaedic Research, Vol. 19		
<i>VM</i>	Barbara Lüssi-Schlatter et al., Die Antimikrobielle Behandlung von Peroralen Enzympräparaten mit Gamma-Strahlen, Pharmazeutisches Institut der Eidgenössischen Technischen Hochschule Zürich Galenische Abteilung, <i>prior art</i> .		
<b>EXAMINER</b> <i>L. McCabe</i>	<b>DATE CONSIDERED</b> <i>9/25/03</i>		

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



#5

SHEET 1 OF 5

**LIST OF PRIOR ART CITED BY  
APPLICANT**  
**(PTO-1449)**

ATTY. DOCKET NO. <b>CI-0008</b>	APPLN. SERIAL NO. <b>09/960,701</b>
APPLICANT <b>David M. MANN et al.</b>	
FILING DATE <b>September 24, 2001</b>	GROUP <b>1741 1744</b>

**U.S. PATENT DOCUMENTS**

EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
LM	4,784,850	11/1998	Abraham			
	4,798,611	01/1989	Freeman, Jr.			
	4,865,602	09/1989	Smestad et al.			
	5,283,034	02/1994	Okrongly et al.			
	5,548,066	08/1996	Leneau et al.			
	5,643,464	07/1997	Rhee et al.			APR 4 2002
	5,989,498	11/1999	Odland			
LM	6,203,544	03/2001	Gotzen			TC 1700

**RECEIVED**

**U.S. PATENT APPLICATION PUBLICATIONS**

	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS	

**U.S. PATENT APPLICATIONS**

	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	

**FOREIGN PATENT DOCUMENTS**

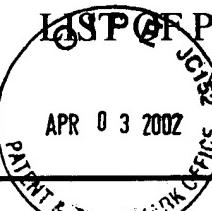
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
LM	919 918 A2	06/1999	Europe (Abstract)			X	
	919 918 A3	06/1999	Europe (Abstract)			X	
	11-216147	08/1999	Japan (Abstract)			X	
	1321420-A	07/1987	Soviet Union (Abstract)			X	
LM	WO 00/25839	03/2000	PCT Int'l (Abstract)			X	

**OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)**

LM	Ozan Akkus et al., Fracture Resistance of Gamma Radiation Sterilized Cortical Bone Allografts, 2001, pps. 927-934, Journal of Orthopaedic Research, Vol. 19
LM	S.R. Aparicio et al., Light and Electron Microscopy Studies on Homograft and Heterograft Heart Valves, 1975, pps. 174-162, J. Path., Vol. 115
LM	J. Baksa et al., The Use of Pig's Skin (xenograft) for the Treatment of Burns, 1976, pps. 138-145, Magyar Traumatologin, Vol. 19

EXAMINER	DATE CONSIDERED
LM	9/25/03

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

 <b>USPTO PRIOR ART CITED BY APPLICANT</b> APR 03 2002 (PTO-1449)			ATTY. DOCKET NO. <b>CI-0008</b>	APPLN. SERIAL NO. <b>09/960,701</b>		
			APPLICANT <b>David M. MANN et al.</b>			
			FILING DATE <b>September 24, 2001</b>	GROUP <b>1741</b>		
<b>FOREIGN PATENT DOCUMENTS</b>						
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation Yes      No
LM	WO 01/08611A1	02/2001	PCT Int'l (Abstract)			X
	WO 01/12318A1	02/2001	PCT Int'l (Abstract)			X
	WO 01/32107A2	05/2001	PCT Int'l (Abstract)			X
	WO 01/32110A2	05/2001	PCT Int'l (Abstract)			X
	WO 01/45720A1	06/2001	PCT Int'l (Abstract)	APP 4	2002	X
	WO 01/49219A1	07/2001	PCT Int'l (Abstract)			X
	WO 01/72233A1	10/2001	PCT Int'l (Abstract)	TC 1700		X
	WO 01/72244A1	10/2001	PCT Int'l (Abstract)			X
LM	WO 01/91818A1	12/2001	PCT Int'l (Abstract)			X
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>						
LM	Seymour S. Block, Disinfection, Sterilization, and Preservation, Fundamental Principles of Activity, Principles of Antimicrobial Activity, Fourth Edition, 1991, pps. 31-33					
	A.J.J.C. Bogers et al., Long-Term Results of the Gamma-Irradiation-Preserved Homograft Monocusp for Transannular Reconstruction of the Right-Ventricular Outflow Tract in Tetralogy of Fallot, 1994, pps. 337-339, Thorac. Cardiovasc. Surgeon, Vol. 42					
	Blakeslee, Sandra, January 20, 2002, The New York Times					
	D.G. Campbell et al., Sterilization of HIV With Irradiation: Relevance to Infected Bone Allografts, 1999, pps. 517-521, Aust. N.Z.J. Surg., Vol. 69					
	Ernest U. Conrad et al., Transmission of the Hepatitis-C Virus by Tissue Transplantation, February 1995, pps. 214-224, The Journal of Bone and Joint Surgery, Vol. 77-A, No. 2					
	A.S. Dagli, Correction of Saddle Nose Deformities by Coral Implantation, 1997, pps. 274-276, Eur Arch Otorhinolaryngol, Vol. 254					
	Defeng et al., Sterilization of Silver-Acidum Pipemedicum Skin for the Treatment of Burns by Radioactive Cobalt-60-Gamma-Ray, 1995, pps. 406 (Abstract)					
	R.J. Donnelly et al., Gamma-radiation of Heart Valves at 4°C; A Comparative Study Using Techniques of Histochemistry and Electron and Light Microscopy, 1978, pps. 95-101					
	Bradley M. Fideler et al., Gamma Irradiation: Effects on Biomechanical Properties of Human Bone-Patellar Tendon-Bone Allografts, 1995, pps. 643-646, American Journal of Sports Medicine, Vol. 23, No. 5					
	Bradley M. Fideler et al., Effects of Gamma Irradiation on the Human Immunodeficiency Virus, July 1994, The Journal of Bone and Joint Surgery, Vol. 76-A, No. 7					
	J.R.P. Gibbons et al., Effects of Gamma Irradiation on the Initial Mechanical and Material Properties of Goat Bone-Patellar Tendon-Bone Allografts, 1991, pps. 209-218, J. Orthop Res, Vol. 9, No. 2					
LM	J.R.P. Gibbons et al., Gamma Ray Sterilisation of Homograft Valves, 1969, pps. 353-358, Bulletin De La Societe Internationale De Chirurgie, No. 3					
EXAMINER	<i>J. McKane</i>		DATE CONSIDERED	9/25/03		

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

APR 03 2002

SHEET 3 OF 5

<b>PATENT &amp; TRADEMARK OFFICE</b> <b>JCT 152</b> <b>DIST OF PRIOR ART CITED BY APPLICANT</b> <b>APR 03 2002</b> <b>(PTO-1449)</b>		ATTY. DOCKET NO. <b>CI-0008</b>	APPLN. SERIAL NO. <b>09/960,701</b>
		APPLICANT <b>David M. MANN et al.</b>	
		FILING DATE <b>S pt mb r 24, 2001</b>	GROUP <b>1741</b>
		<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>	
<b>UM</b>	M.J. Goertzen et al., Anterior Cruciate Ligament Reconstruction Using Cryopreserved Irradiated Bone-ACL-Bone-Allograft Transplants, 1994, pps. 150-157, Knee Surgery Sports Traumatology Arthroscopy, Vol. 2		
	M.J. Goertzen et al., Sterilisation of Canine Anterior Cruciate Allografts by Gamma Irradiation in Argon, March 1995, pps. 205-212, The Journal of Bone and Joint Surgery, Vol. 77-B, No. 2		
	Slawomir Gregorczyk et al., Strength of Lyophilized and Irradiated Cortical Bone of the Human Femur, 1995, pps. 129-133, Chir. Narz. Ruchu Ortop. Pol., Lx 2		
	F.W. Hehrlein et al., Biochemische Veränderungen an Heterologen Aortenklappentransplantaten nach Anwendung Verschiedener Sterilisationsverfahren, pps. 1183-1185, Langenbecks Arch. Chir., Bd. 325 (Kongrebericht) (English Summary found at page 1183), <i>prior art</i> .		
	F.W. Hehrlein et al., Morphologische Untersuchungen an Heterologen Herzkappentransplantaten Unter Verschiedenen Sterilisationsbedingungen, pps. 244-251 (English Summary found at page 250), <i>prior art</i> .		
	Richard Hinton et al., A Biomechanical Analysis of Solvent-dehydrated and Freeze-Dried Human Fascia Lata Allografts, 1992, pps. 607-612, The American Journal of Sports Medicine, Vol. 20, No. 5		
	M. Horowitz, Sterilization of Homograft Ossicles by Gamma Radiation, November 1979, pps. 1087-1089, The Journal of Laryngology and Otology, Vol. 93		
	Shinichiro Ijiri et al., Effect of Sterilization on Bone Morphogenetic Protein, 1994, pps. 628-636, Journal of Orthopaedic Research, Vol. 12		
	A.S. Imamáliev et al., Biological Properties of Bone Tissue Conserved in Plastic Material and Sterilized With Gama Rays, 1974, pps. 129-135, ACTA, Chirurgiae Plasticae, Vol. 16, No. 3		
	A. Ingegneri et al., An 11-Year Assessment of 93 Flash-frozen Homograft Valves in the Aortic Position, 1979, pps. 304-307, Thorac. Cardiovasc. Surgeon, Vol. 27		
	J. Jerosch et al., A New Technique for Bone Sterilization, 1989, pps. 117-120, Biomedizinische Technik, Band 34, Heft 5		
	J. Jerosch et al., Influence of Different Rehydration Periods on the Stability and the Water Content of Bone Allografts After Lyophilization, Gamma-Irradiation, and Lipid Extraction, 1994, pps. 335-341, Z. Orthop., Vol. 132		
	L. Kerboull et al., In Vitro Study of the Influence of Various Conservation Methods on the Mechanical Properties of Patellar Tendon Allografts, 1991, pps. 751-762, Chirurgie, Vol. 117		
	Andrezej Komender et al., Some Biological Properties of Bovine Trypsinized Fascia Xenografts, 1981, pps. 485-489, Archivum Immunologiae et Therapiae Experimentalis, Vol. 29		
	Andrezej Komender et al., Some Biological Properties of Preserved Bovine Fascia Enriched With Pulverized Calf Cartilage, 1984, pps. 211-219, Archivum Immunologiae et Therapiae Experimentalis, Vol. 32		
	J.F. Kouvalchouk et al., The Use of Sterilized Bone Allografts in Reconstruction After Tumour Resection, 1986, pps. 393-401, Revue de Chirurgie Orthopedique, Vol. 72		
	Linberg et al., Irradiated Homologous Cartilage For Orbital Reconstruction, July 1980, pps. 457-462, Ophthalmic Surgery, Vol. 11		
	<b>UM</b> McDowell, Sandra, Irradiated Cartilage, Spring 1988, pps. 14-15, Plastic Surgical Nursing		
	<b>EXAMINER</b> <i>L. McLane</i>	<b>DATE CONSIDERED</b> <i>9/25/03</i>	

**RECEIVED**

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

APR 4 2002

1700

O 1152  
APR 03 2002  
PATENT & TRADEMARK OFFICE

SHEET 4 OF 5

**LIST OF PRIOR ART CITED BY  
APPLICANT**  
**(PTO-1449)**

ATTY. DOCKET NO. <b>CI-0008</b>	APPLN. SERIAL NO. <b>09/960,701</b>
APPLICANT <b>David M. MANN et al.</b>	
FILING DATE <b>Sept 24, 2001</b>	GROUP <b>1741</b>

**OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)**

W	A. Maeda et al., Effects of Solvent Preservation With or Without Gamma Irradiation on the Material Properties of Canine Tendon Allografts, 1993, pps. 181-189, Journal of Orthopaedic Research, Vol. 11
	Akira Maeda et al., Solvent-dried and Gamma-irradiated Tendon Allografts in Rats, July 1998, pps. 731-736, The Journal of Bone and Joint Surgery, Vol. 80-B, No. 4
	S. Malawski et al., The Use of Dry-Freezed Bone Grafts Sterilized by Gamma Rays in Orthopaedic Surgery, 1969, pps. 61-68, Chir. Narz. Ruchu Ortop.
	Ken Nakata et al., Reconstruction of the Lateral Ligaments of the Ankle Using Solvent-dried and Gamma-Irradiated Allogeneic Fascia Lata, May 2000, pps. 579-582
	Maria Esther Martinez Pardo et al., Clinical Application of Amniotic Membranes on a Patient With Epidermolysis Bullosa, 1999, pps. 68-73, Annals of Transplantation, Vol. 4, No. 3-4
	Jan Parizek et al., Duraplasty With Pretreated Freeze-Dried Sterilized Human Dura Mater, 1990, pps. 135-143, Sbor. ved. Praci LF UK Hradec Kralove, Vol. 33
	Jan Parizek et al., Ovine Pericardium: A New Material For Duraplasty, 1996, pps. 508-513, J. Neurosurg., Vol. 84
	Patel et al., Effect of Gamma Radiation and Ethylene Oxide on Papain, 1979, pps. 81-83, Indian. J. Pharm. Sci., Vol. 41, No. 2
	L.V. Polezhaeu et al., Repair of Cranial Defects With Regenerating Bone in Grafting Gamma-Irradiated Bone Filings, pps. 57-60, prior art.
	Donald J. Prolo et al., Composite Autogeneic Human Cranioplasty: Frozen Skull Supplemental With Fresh Iliac Corticocancellous Bone, December 1984, pps. 846-851, Neurosurgery, Vol. 15, No. 6
	Donald J. Prolo et al., Superior Osteogenesis in Transplanted Allogeneic Canine Skull Following Chemical Sterilization, August 1982, pps. 230-242, Clinical Orthopaedics and Related Research, No. 168
	T.J. Rasmussen et al.; The Effects of 4 Mrad of Gamma-Irradiation on the Initial Mechanical Properties of Bone-Patellar Tendon-Bone Grafts, 1994, pps. 188-197, The Journal of Arthroscopic and Related Surgery, Vol. 10, No. 2
	S.C. Roe et al., The Effect of Gamma Irradiation on a Xenograft Tendon Bioprothesis, 1992, pps. 149-154, Clinical Materials, Vol. 9
	D. Tylman, Mechanical Character of Liofilized and Sterilized by Gamma-Rays Bone Tissue, 1996, pps. 229-234, Chirurgia Narzadow Ruchu I, Ortopedia Polska
	W. Welch, A Comparative Study of Different Methods of Processing Aortic Homografts, 1969, pps. 746-749, Thorax, Vol. 24
	J.M. White et al., Sterilization of Teeth by Gamma Radiation, September 1994, pps. 1560-1567, J. Dent. Res., Vol. 73, No. 9
	Qi Zhang et al., Ethylene Oxide Does Not Extinguish the Osteoinductive Capacity of Demineralized Bone, 1997, pps. 104-108, Acta Orthop Scand, Vol. 68, No. 2
W	Yongxing Zhang et al., A Comprehensive Study of Physical Parameters, Biomechanical Properties and Statistical Correlations of Iliac Crest Bone Wedges Used in Spinal Fusion Surgery, 1994, pps. 304-308, Spine, Vol. 19, No. 3

EXAMINER

L. mckay

DATE CONSIDERED

9/25/03

RECEIVED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not consider d. Include copy of this form with next communication to Applicant.

APR 1 2002  
TC 1700

		ATTY. DOCKET NO. <b>CI-0008</b>	APPLN. SERIAL NO. <b>09/960,701</b>
		APPLICANT <b>David M. MANN et al.</b>	
		FILING DATE <b>September 24, 2001</b>	GROUP <b>1741</b>
		<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>	
<i>LM</i>	A.A. Belov et al., The Influence of $\gamma$ -radiation on Enzyme Activity of Collalitin in the Process of Storage, 12/07/89, pps. 519-521, All-Union Research Institute of Textile and Haberdashery Industry, Moscow		
	R.I. Vaida et al., Structural-Functional Peculiarities of Myocardial Capillaries After Resection of the Lungs, 10/21/86, pps. 68-73		
	Martindale's Extra Pharmacopoeia, Glucose, pp. 1265, <i>prior art</i> .		
	The Merck Index, Eleventh Edition Glucose, pps. 4353-4354, <i>prior art</i> .		
	G.L. Moore et al., Effects of 4000 Rad. Irradiation on the In Vitro Storage Properties of Packed Red Cells, Nov-Dec 1985, pps. 583-585, Final Rept., Pub. In Transfusion, Vol. 25, No. 6 (Abstract)		
	Shcheglova et al. The Effect of the Power of Gamma-Radiation on the Radiation Dose in the Sterilization of Drugs, 1984, pps. 730-732, Khim-Farm Zh, Vol. 18, No. 6 (Abstract)		
<i>LM</i>	G.A. Yarygina, Dose Rate Effect on Survival of Microorganisms Used as Test-Cultures in Radiation Sterilization of Medical Products, 1973, pps. 32-39, Radiats. Tekh., No. 9 (Abstract)		
<p style="text-align: center;"><b>RECEIVED</b></p> <p style="text-align: center;">APR 4 2002</p> <p style="text-align: center;"><b>TC 1700</b></p>			
<b>EXAMINER</b> <i>L. McCone</i>	<b>DATE CONSIDERED</b>	<i>9/25/03</i>	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



#6

SHEET 1 OF 1

**LIST OF PRIOR ART CITED BY  
APPLICANT  
(PTO-1449)**

ATTY. DOCKET NO. <b>CI-0008</b>	APPLN. SERIAL NO. <b>09/960,701</b>
APPLICANT(S) <b>David M. MANN et al.</b>	
FILING DATE <b>Sept 24, 2001</b>	GROUP <b>1741 1744</b>

**OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)**

LM

O. Cornu et al., Effect of Freeze-Drying and Gamma Irradiation on the Mechanical Properties of Human Cancellous Bone, 2000, pps. 426-431, Journal of Orthopaedic Research, Vol. 18

Anna Dziedzic-Goclawska et al., Effect of Radiation Sterilization on the Osteoinductive Properties and the Rate of Remodeling of Bone Implants Preserved by Lyophilization and Deep-Freezing, November 1991, pps. 30-37, Clinical Orthopaedics and Related Research, No. 272

Ole T. Jensen et al., Vertical Guided Bone-Graft Augmentation in a New Canine Mandibular Model, 1995, pps. 335-343, The International Journal of Oral and Maxillofacial Implants, Vol. 10, No. 3

Ronald W. Katz et al., Radiation-Sterilized Insoluble Collagenous Bone Matrix is a Functional Carrier of Osteogenin for Bone Induction, 1990, pps. 183-185, Calcified Tissue International, Vol. 47

Everard Munting et al., Effect of Sterilization on Osteoinduction; 1988, pps. 34-38, Acta Orthop Scand, Vol. 59, No. 1

P.A. Puolakkainen et al., The Effect of Sterilization on Transforming Growth Factor  $\beta$  Isolated From Demineralized Human Bone, 1993, pps. 679-685, Transfusion, Vol. 33, No. 8

U. Ripamonti et al., Long-Term Evaluation of Bone Formation by Osteogenic Protein 1 in the Baboon and Relative Efficacy of Bone-Derived Bone Morphogenetic Proteins Delivered by Irradiated Xenogeneic Collagenous Matrices, 2000, pps. 1798-1809, Journal of Bone and Mineral Research, Vol. 15, No. 9

A. Salehpour et al., Dose-Dependent Response of Gamma Irradiation on Mechanical Properties and Related Biochemical Composition of Goat Bone-Patellar Tendon-Bone Allografts, 1995, pps. 898-906, Journal of Orthopaedic Research, Vol. 13

Nikolaus Schwarz et al., Irradiation-sterilization of Rat Bone Matrix Gelatin, 1988, pps. 165-167, Acta Orthop Scand, Vol. 59, No. 2

C.W. Smith et al., Mechanical Properties of Tendons: Changes With Sterilization and Preservation, February 1996, pps. 56-61, Journal of Biomechanical Engineering, Vol. 118

Yukiyoshi Toritsuka et al., Effect of Freeze-Drying or  $\gamma$ -Irradiation on Remodeling of Tendon Allograft in a Rat Model, 1997, pps. 294-300, Journal of Orthopaedic Research, Vol. 15

Konrad Wangerin et al., Behavior of Differently Sterilized Allogenic Lyophilized Cartilage Implants in Dogs, 1987, pps. 236-242, J. Oral Maxillofac Surg, Vol. 45

LM S. Wientroub et al., Influence of Irradiation on the Osteoinductive Potential of Demineralized Bone Matrix, 1988, pps. 255-260, Calcified Tissue International, Vol. 42

*RECEIVED*  
APR 24 2002  
TC 1700

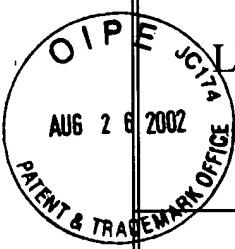
EXAMINER

*L.mckane*

DATE CONSIDERED

9/22/03

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



**LIST OF PRIOR ART CITED BY  
APPLICANT  
SUBSTITUTION FOR  
(PTO-1449)**

ATTY. DOCKET NO. APPLN. SERIAL NO.  
**CI-0008** **09/960,701**

APPLICANT  
**David M. MANN et al.**

FILING DATE GROUP  
**September 24, 2001** **1744 1744**

**U.S. PATENT DOCUMENTS**

*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
LM	A1	4,336,247	06/1982	Eriksen	—	—	
	A2	4,931,361	06/1990	Baldeschwieler et al.	—	—	
	A3	5,012,503	04/1991	Nambu et al.	—	—	
	A4	5,044,091	09/1991	Ueda et al.	—	—	
	A5	5,856,172	01/1999	Greenwood et al.	—	—	AUG 27 2002
	A6	6,010,719	01/2000	Remon et al.	—	—	
	A7	6,060,233	05/2000	Wiggins	—	—	
LM	A8	6,258,821	07/2001	Stogniew et al.	—	—	
	A9				—	—	
	A10				—	—	
	A11				—	—	

**RECEIVED**

**AUG 27 2002**

**TC 1700**

**U.S. PATENT APPLICATION PUBLICATIONS**

*EXAMINER'S INITIALS	CITE NO.	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS	FILING DATE
	B1						

**U.S. PATENT APPLICATIONS**

*EXAMINER'S INITIALS	CITE NO.	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	FILING DATE
	C1						

**FOREIGN PATENT DOCUMENTS**

*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*DATE	*COUNTRY	CLASS	SUBCLASS	Translation
							Yes No
	D1						
	D2						
	D3						
	D4						
	D5						

**OTHER ART**

*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
LM	E1	Blanchy, B.B. et al., Immobilization of Factor VIII on Collagen Membranes, J. Biomedical Materials Research, 20:469-479 (1986) (John Wiley & Sons, Inc.)
LM	E2	Boyer, T.D. et al., Radiation Inactivation of Microsomal Glutathione S-Transferase, The Journal of Biological Chemistry, 261:16963-16968 (1986)

EXAMINER *L. McKane* DATE CONSIDERED *9/22/03*

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



ATTY. DOCKET NO.  
CI-0008

APPLN. SERIAL NO.  
09/960,701

APPLICANT  
David M. MANN et al.

FILING DATE  
September 24, 2001

GROUP  
1741 1744

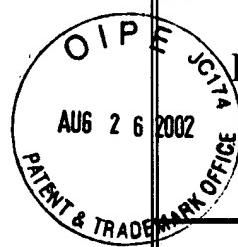
LIST OF PRIOR ART CITED BY  
APPLICANT  
SUBSTITUTION FOR  
(PTO-1449)

RECEIVED  
AUG 27 2002  
TC 1700

OTHER ART

*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
LM	E3	Chanderkar, L.P. et al., The Involvement of Aromatic Amino Acids in Biological Activity of Bovine Fibrinogen as Assessed by Gamma-Irradiation, Radiation Research, 65:283-291 (1976) (Academic Press, Inc.)
	E4	Chanderkar, L.P. et al., Radiation-Induced Changes In Purified Prothrombin and Thrombin, Biochimica et Biophysica Acta, 706:1-8 (1982) (Elsevier Biomedical Press)
	E5	Chin, S. et al., Virucidal Treatment of Blood Protein Products With UVC Radiation, Photochemistry and Photobiology, 65:432-435 (1997) (American Society for Photobiology)
	E6	Ghosh, M.M. et al., A Comparison of Methodologies for the Preparation of Human Epidermal-Dermal Composites, Annals of Plastic Surgery, 39:390-404 (1997) (Lippincott-Raven Publishers)
	E7	Goertzen, M.J. et al., Anterior Cruciate Ligament Reconstruction Using Cryopreserved Irradiated Bone-ACL-Bone-Allograft Transplants, Knee Surg. Sports Traumatol. Arthroscopy, 2:150-157 (1994) (Springer-Verlag)
	E8	Hsiue, G. et al., Absorbable Sandwich-Like Membrane for Retinal-Sheet Transplantation, pp.20-25 (2002) (Wiley Periodicals, Inc)
	E9	Jensen, J. et al., Membrane-bound Na, K-ATPase: Target Size and Radiation Inactivation Size of Some of Its Enaymatic Reactions, J. Biological Chemistry, 263:18063-18070 (1988) (Am. Soc. for Biochem. and Mol. Biol.)
	E10	Kamat, H.N. et al., Correlation of Structural Alterations in Bovine Fibrinogen with Loss of Clotting Properties After Gamma Irradiation, Radiation Research, 49:381-389 (1972) (Academic Press, Inc.)
	E11	Kempner, E.S. et al., Effect of Environmental Conditions on Radiation Target Size Analyses, Analytical Biochemistry, 216:451-455 (1994)
	E12	Kempner, E.S. et al., Radiation-Damaged Tyrosinase Molecules are Inactive, Biophysical Journal, 55:159-162 (1989) (Biophysical Society)
	E13	Kuijpers, A.J. et al., <i>In vivo</i> Compatibility and Degradation of Crosslinked Gelatin Gels Incorporated in Knitted Dacron, pp.137-144 (2000) (John Wiley & Sons, Inc.)
	E14	Le Maire, M. et al., Effects of Ionizing Radiations on Proteins, Journal of Biochem., 267:431-439 (1990)
	E15	Ma, J.T. et al., Functional Size Analysis of F-ATPase from <i>Escherichia coli</i> by Radiation Inactivation, The Journal of Biological Chemistry, 268:10802-10807 (1993) (The Am. Soc. for Biochem. and Mol. Bio., Inc.)
	E16	Marx, G. Protecting Fibrinogen with Rutin During UVC Irradiation for Viral Inactivation, Photochemistry and Photobiology, 63:541-546 (1996) (American Society for Photobiology)
	E17	Nagrani, S. et al., The Radiation-Induced Inactivation of External Yeast Invertase in Dilute Aqueous Solution, Int. J. Radiat. Biol., 55:191-200 (1989) (Taylor & Francis Ltd.)
	E18	Nielsen, M. et al., The Apparent Target Size of Rat Brain Benzodiazepine Receptor, Acetylcholinesterase, and Pyruvate Kinase Is Highly Influenced by Experimental Conditions, The Journal of Biological Chemistry, 263:11900-11906 (1988) (The American Society for Biochemistry and Molecular Biology, Inc.)
LM	E19	Potier, M. et al., Radiation Inactivation of Proteins: Temperature-Dependent Inter-Protomeric Energy Transfer in Ox Liver Catalase, Biochem. J., 298:571-574 (1994)
EXAMINER	L. McCane	DATE CONSIDERED 9/22/03

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



**LIST OF PRIOR ART CITED BY  
APPLICANT  
SUBSTITUTION FOR  
(PTO-1449)**

ATTY. DOCKET NO.  
CI-0008APPLN. SERIAL NO.  
09/960,701APPLICANT  
**David M. MANN et al.**FILING DATE  
**September 24, 2001**GROUP  
**1744-1744****OTHER ART**

*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
LM	E20	Sakai, T. et al., Microbiological Studies on Drugs and Their Raw Materials. IV. Sterilization of Microbial Contaminants in Enzyme Powder by Gamma Irradiation, Chem. Pharm. Bull., 26:1130-1134 (1978)
	E21	Salim-Hanna, M. et al., Free Radical Scavenging Activity Of Carnosine, Free Rad. Res. Comms., 14:263-270 (1991) (Harwood Academic Publishers GmbH)
	E22	Song, K.B. et al., Effect of Gamma-irradiation on the Physicochemical Properties of Blood Plasma Proteins, 2002 Annual Meeting and Food Expo-Anaheim, California, Session 30C-1, Food and Chemistry: Proteins, (June 2002) (Abstract)
	E23	Suomela, H., Inactivation of Viruses in Blood and Plasma Products, Transfusion Medicine Reviews, 7:42-57 (1993) (W.B. Saunders Company)
	E24	(Abstract of EP0919198A2 and EP0919198A3 (Delphion-DERABS Abstract # G1999-304614)) prior art.
	E25	Website: <a href="http://www.wslfweb.org/docs/dstp2000.dtopdf/19-MD.pdf">www.wslfweb.org/docs/dstp2000.dtopdf/19-MD.pdf</a> (Defense Science and Technology Plans, (February 2000) p. 176, Section II, MD.03, U.S. Department of Defense Deputy Under Secretary of Defense (Science and Technology))
	E26	Website: <a href="http://www.usacc.org/atacc/ppt.html">www.usacc.org/atacc/ppt.html</a> , (Advanced Technology Applications for Combat Casualty Care, 2001 Presentations, US Army Medical Research and Material Command Combat Casualty Care Research Program (2001))
	E27	Website: <a href="http://www.usacc.org/RevisedStepB.html">www.usacc.org/RevisedStepB.html</a> , Bakaltcheva, I. et al., (FY01 Request for Proposals-Intramural-Revised 2, Combat Casualty Care Research Program, (2002))
	E28	Website: <a href="http://www.benvue.com/history/history_content.html">www.benvue.com/history/history_content.html</a> , (2002)
	E29	Website: <a href="http://www.phase-technologies.com/html/vol.2no1.html">www.phase-technologies.com/html/vol.2no1.html</a> , Jennings, T.A., (Glossary of Terms for Lyophilization) (1999)
	E30	Website: <a href="http://www.phase-technologies.com/html/vol.1no9.html">www.phase-technologies.com/html/vol.1no9.html</a> , Jennings, T.A., (Overview of the Lyophilization Process) (1998)
	E31	Website: <a href="http://www.phase-technologies.com/html/vol.1no2.html">www.phase-technologies.com/html/vol.1no2.html</a> , Jennings, T.A., (Role of Product Temperature in the Lyophilization Process) (1998)
	E32	Website: <a href="http://www.phase-technologies.com/html/vol.2no2.html">www.phase-technologies.com/html/vol.2no2.html</a> , Jennings, T.A., (What I Wish I Knew About Lyophilization) (1999)
	E33	Website: <a href="http://www.phase-technologies.com/html/vol.1no7.html">www.phase-technologies.com/html/vol.1no7.html</a> , Jennings, T.A., (Which Shelf Temperature During Lyophilization?) (1998)
	E34	Website: <a href="http://www.phase-technologies.com/html/vol.1no10.html">www.phase-technologies.com/html/vol.1no10.html</a> , Jennings, T.A., (Yes, You have no Eutectic) (1998)
LM	E35	

EXAMINER

*L. McCane*

DATE CONSIDERED

*9/22/03*

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

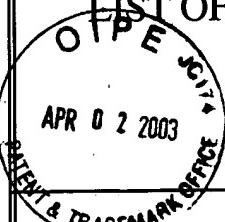
RECEIVED

AUG 27 2002

TC 1700

<p style="text-align: center;"><b>LIST OF PRIOR ART CITED BY APPLICANT</b> <b>(PTO-1449)</b></p> <p style="text-align: right;">FEB 25 2003</p> <p style="text-align: right;">O I P E S C I T A P A T E N T &amp; T R A D E M A R K O F F I C E</p>				ATTY. DOCKET NO. <b>CI-0008</b>		APPLN. SERIAL NO. <b>09/960,701</b>	
				APPLICANT(S) <b>David M. MANN, William N. DROHAN, Martin J. MACPHEE and Wilson BURGESS</b>		FILING DATE <b>September 24, 2001</b>	
<b>U.S. PATENT DOCUMENTS</b>							
EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE	
LM	4,994,237	02/19/91	LOGIN et al.	422	21	11/13/89	
LM	6,383,732 B1	05/07/02	STONE	435	1.1	06/01/00	
LM	4,727,027	02/23/88	WIESEHABHN et al.	435	173	10/07/85	
<b>U.S. PATENT APPLICATION PUBLICATIONS</b>							
	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS		
<b>U.S. PATENT APPLICATIONS</b>							
	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS		
<b>FOREIGN PATENT DOCUMENTS</b>							
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>							
EXAMINER <i>Leigh McCane</i>	DATE CONSIDERED <i>9/22/03</i>						

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

<b>LIST OF PRIOR ART CITED BY APPLICANT</b> <b>(PTO-1449)</b> 				ATTY. DOCKET NO. <b>CI-0008</b>	APPLN. SERIAL NO. <b>09/960,701</b>	
				APPLICANT(S) <b>David M. MANN, William N. DROHAN, Martin J. MACPHEE and Wilson BURGESS</b>		
				FILING DATE <b>September 24, 2001</b>	GROUP <b>1744 1744</b>	
<b>U.S. PATENT DOCUMENTS</b>						
EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
<b>U.S. PATENT APPLICATION PUBLICATIONS</b>						
	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS	
<b>U.S. PATENT APPLICATIONS</b>						
	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	
<b>FOREIGN PATENT DOCUMENTS</b>						
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation Yes No
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>						
LM	Robert J. Woods, "Food Irradiation," Endeavor, New Series, Vol. 18, No. 3, 1994, pp. 104-108.					
LM	A. Dziedzic-Goclawska et al., "Sterilisation of Tissue Allografts," Advances in Tissue Banking, Vol. 1, pp. 261-321, prior art.					
LM	M.J. Goertzen et al., "Sterilisation of Canine Anterior Cruciate Allografts by Gamma Irradiation in Argon," Journal of Bone and Joint Surgery (Corrections), Vol. 77-B, No. 2, March 1995, pp. 205-212.					
EXAMINER	<i>L. McKee</i>					
	DATE CONSIDERED <b>9/22/03</b>					

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

<b>LIST OF PRIOR ART CITED BY APPLICANT (PTO-1449)</b> 			ATTY. DOCKET NO. <b>CI-0008</b>		APPLN. SERIAL NO. <b>09/960,701</b>	
			APPLICANT(S) <b>David M. MANN, William N. DROHAN, Martin J. MACPHEE and Winslow BURGESS</b>			
			FILING DATE <b>September 24, 2001</b>	GROUP <b>1741</b>		
<b>U.S. PATENT DOCUMENTS</b>						
EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
LM	6,346,216 B1	02/12/02	KENT	422	22	05/15/00
	6,312,931 B1	11/06/01	O'DWYER et al.	435	173.1	02/11/00
	6,358,284 B1	03/19/02	FEARNOT et al.	623	23.72	06/02/99
	6,375,989 B1	04/23/02	BADYLAK et al.	424	551	06/10/99
	6,384,419 B1	05/07/02	PURTLE	250	526	03/30/00
	6,461,630 B1	10/08/02	TUCKER et al.	424	423	11/30/99
	6,485,723 B1	11/26/02	BADYLAK et al.	424	93.7	05/08/00
	4,877,866	10/31/89	RUDNICK et al.	530	387	11/18/87
LM	6,383,810 B2	05/07/02	FIKE et al.	435	384	02/13/98
<b>U.S. PATENT APPLICATION PUBLICATIONS</b>						
	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS	
LM	US2002/0064807 A1	04/30/02	BADYLAK et al.	435	34	11/14/01
	US2002/0106394 A1	08/08/02	TUCKER et al.	424	423	09/18/01
	US2002/0188319 A1	12/12/02	MORRIS et al.	606	213	06/10/02
	US2003/0068815 A1	04/10/03	STONE et al.	435	325	05/17/02
LM	US2001/0049141 A1	12/06/01	FIKE et al.	435	384	02/13/98
<b>U.S. PATENT APPLICATIONS</b>						
	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	
<b>FOREIGN PATENT DOCUMENTS</b>						
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation Yes No
LM	EP0808167 B1	06/05/02	EPO	—	—	
LM	EP0820301 B1	07/24/02	EPO	—	—	
LM	WO 00/28552	05/18/00	PCT	—	—	
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>						
Robert J. Woods, "Food Irradiation," Endeavor, New Series, Vol. 18, No. 3, 1994, pp. 104-108.						
A. Dziedzic Goelawska et al., "Sterilisation of Tissue Allografts," Advances in Tissue Banking, Vol. 1, pp. 261-321.						
M.J. Goertzen et al., "Sterilisation of Canine Anterior Cruciate Allografts by Gamma Irradiation in Argon," Journal of Bone and Joint Surgery (Corrections), Vol. 77-B, No. 2, March 1995, pp. 205-212.						
EXAMINER <i>L. McKane</i>	DATE CONSIDERED <i>9/22/03</i>					

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.